K072456

Attachment 4:

510(K) SUMMARY

MAY - 8 2008

Date of Summary: August 24, 2007

I. **Applicant:**

Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, CA 91301
Tel: (866) 422-5337 Fax: (818) 879-6556

Contact:

Christine Emanuel
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, CA 91301
Tel: (866) 422-5337 Fax: (818) 879-6556
cemanuel@west.net

2. **Device Name:** Surgical Mesh (878.3300)
Trade Name: Desara
Common Name: Surgical Mesh

3. **Predicate Device**
Caldera T-Sling
K050516
Feb. 3, 2006

4. **Description of Device**
The Caldera Desara Mesh is sterile, single-use pubourethral sling used to provide support in the pelvic region to treat stress urinary incontinence, mixed incontinence, and vaginal vault prolapse. The device is manufactured out of a monofilament polypropylene yarn, which is knitted into a mesh. The device has integral sleeve and sutures to assist the surgeon in placement of the device. The sleeve and sutures are removed after placement of the device.

The Desara Mesh device is a modification to the Caldera T-Sling, used for the same Indications for Use and manufactured out of the same mesh material, a monofilament polypropylene mesh

5. **Intended Use of Device**
The Desara Mesh is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

6. **Summary of Technological Characteristics**
The Caldera Desara device has the same materials and design as the Caldera T-Sling and has the same technological characteristics. The changes to the Desara Mesh are minor and are primarily related to changes in suppliers as well as minor changes to mesh configuration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2008

Caldera Medical, Inc.
% Ms. Mara Korsunsky
Quality Assurance and Regulatory
Affairs Manager
28632 Roadside Drive, Suite 260
Agoura Hills, California 91301

Re: K072456
Trade/Device Name: Desara™ Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 7, 2008
Received: April 8, 2008

Dear Ms. Korsunsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2:

Indications for Use

510(k) Number (if known): K072456

Device Name: Desara™ Implant

Indications for Use:

The Desara™ Mesh is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072456